Applicant: Edwin Madison et al. Attorney's Docket No.: 17106-024001

Serial No.: 10/099,700 Filed: March 13, 2002

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## **REMARKS**

A check in the amount of \$1042.00 for the Issue Fee for a small entity, publication fee and an advance order of 14 copies of the issued patent accompanies this response. Any fees that may be due in connection with this paper or this application during its entire pendency may be charged to Deposit Account No. 06-1050. If a Petition for extension of time is needed, this paper is to be considered such Petition.

Claims 1, 2, 4, 5, 8, 9, 18, 19, 50-53, 59-61, 65-67, 69-79, 82 and 123-128 are allowed. Claims 2, 19 and 66 are amended herein to replace "polypeptide" with —protease— for proper antecedent basis. Claim 61 is amended to replace "array" with —support— to render the claim properly dependent upon claim 60, which is directed to a support. The amendments are further to those made by the Examiner in the Notice of Allowance dated January 25, 2006, in order to provide consistency in terminology between these claims and their respective base claims.

## Comments on Examiner's Statement of Reasons for Allowance

Applicant recognizes that in accordance with M.P.E.P. § 1302.14, the Examiner's reasons for allowance need not set forth all of the details as to why the claims are allowed. In the above-referenced application, Applicant does not concede that the Examiner's stated reasons for allowance are the only reasons for which the claims are allowable. The claims may be patentable for additional reasons.

The Examiner has withdrawn the utility rejections against claims 65 – 67 and 69 – 72. The Examiner has agreed with our arguments with regard to the propriety of the rejections and cites that assays to identify compounds that inhibit the activity of MTSP7 possess the requisite patentable utility. The Examiner provides reasons for withdrawing the rejections as based on the specification's disclosure of differential expression of MTSP7 in three specific cancer cell lines arising from different tissues. Further, the Examiner agrees that there is a specific and substantial utility in assays to find binding partners and inhibitors for the MTSP7 protease to establish the location within these cells lines where the protease or its zymogen form reside and to measure activity of the protease or its zymogen form in these cells. The Examiner also agrees that binding partners and inhibitors of the proteases may also be identified and selected in order to purify the protease from cell lysates or *in vitro* transcription/translation system.

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We contend that there exists and the application provides a nexus between protease expression and cancer development and progression. Further, the instant application provides adequate evidence that the MTSP7 and its inhibitors are involved in the control of cancer cell invasion, metastatic spread and neovascularization of tumors. The assays provided identify compounds that inhibit MTSP7 activity and that such compounds are candidate anti-tumor agents by virtue of their inhibition of the activity of MTSP7. Therefore, the assays provide a public benefit and possess the requisite patentable utility.

With respect to the rejections pursuant to 35 U.S.C. §102(e)(1), the Examiner amended claims 4 and 5 to avoid the disclosure of Alsobrook *et al*. We contend that the instantly claimed polypeptides differ from the polypeptides disclosed in Alsobrook. Alsobrook does not disclose a polypeptide that contains **only the MTSP7 protease domain** and nothing more nor does Alsobrook disclose a polypeptide that contains the MTSP7 protease domain and no other MTSP7 portions. Alsobrook also does not disclose a polypeptide where the only MTSP7 portion of the polypeptide is the MTSP7 protease domain or a catalytically active portion thereof where the protease domain has the sequence of amino acids encoded by the sequence of nucleotides set forth in SEQ ID No. 17. Alsobrook only discloses a polypeptide the includes a protease domain, but does not teach isolation of the protease domain from the rest of the polypeptide. Hence it does not disclose all elements as claimed. Applicant refers to the responses of record for further discussion on this point.

The Examiner rejoined claims 73 – 82 withdrawn from examination but subject to rejoinder. The Examiner amended claims 73, 74 and 76 – 79 to "ensure that the allowed method claims describe a specific protease and include a measuring or comparison step to state a complete method." The Examiner restated claim 61 to effect agreement with the specification as well as with the base claim and intervening claims. As part of the Examiner's amendment, he replaced the phrase "The support of claim..." with —The array of claim...—. Such an amendment renders the claim improperly dependent. Thus, claim 61 is amended to its original form to recite —The support of claim...—. The Examiner also restated claims 50, 59, 65, 73 and 79 to depend from either claim 1 or claim 5.

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Applicant respectfully requests entry of the above amendments and remarks into the file history of the above-captioned application.

Respectfully submitted, /

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